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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,371	12/10/2001	Ian R. Reid	HO-P02194US0	6234

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,371	REID, IAN R.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,11-15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,9,11-15 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed August 22, 2005, and amendment and response to the Final Office Action (mailed May 16, 2005), filed August 22, 2005 wherein no amendment is filed.

Claims 5, 10, 16-21 are cancelled previously.

Currently, claims 1-4, 6, 8-9, 11-15, and 17-22 are pending in this application and under examination herein.

Applicant's declaration of Dr. Ian R. Reid (inventor), submitted August 22, 2005 in under 37 CFR 1.132, is acknowledged and will be further discussed below.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-9, 11-15, and 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over under 35 U.S.C. 103(a) as being unpatentable over Pak et al. (US 4,851,221 of record) in view of the Merck Manual of Diagnosis and Therapy (17th ED) (1999) (PTO-892) and Applicant's admission regarding the prior art in the specification (see page 2).

Pak et al. discloses that administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia and hypertension (see col.1 lines 49-50, 63-68; col.3 lines 42-43, 46; col.8 line 35-36; col.9 line 50-67; claim 20). Pak et al. disclose a daily administration. The calcium citrate composition of Pak et al. is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide (see abstract, and claim 18-20).

Note that Pak et al. discloses the same effective amounts or doses of calcium citrate to be administered to the postmenopausal woman as instantly claimed.

Pak et al. does not expressly disclose the employment of the calcium composition in methods of increasing a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in a postmenopausal woman. Pak et al. does not expressly if the high-density lipoprotein level in plasma is increased, the administering the calcium composition for at least about two months.

However, as discussed above, the host, a postmenopausal woman, and the amount and calcium citrate, are same as instantly claimed. Moreover, it is well known that cardiovascular diseases becomes more prevalent after menopause according to the Merck Manual of Diagnosis and Therapy. It is also well-known that the various conditions associated to a postmenopausal woman also include hypercholesterol levels due to menopause in need of increasing a high-density lipoprotein level (HDL) in plasma or lowering low-density lipoprotein level (LDL), or increasing a ratio of HDL to LDL in said postmenopausal woman.

Hence, the patient population in Pak et al. is deemed to encompass or overlap or even as same patient herein in need of increasing HDL level in plasma.

Thus, Pak's method would inherently increase a high-density lipoprotein level (HDL) in plasma or a ratio of HDL to LDL in a postmenopausal woman. The increase of HDL would have been inherent by administration of calcium citrate in 1 g dose per day. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Further, Applicant clearly admits and acknowledges in the specification regarding the prior art that:

"Calcium supplementation is widely recommended and used amongst postmenopausal women for prevention of osteoporosis (Genant et al., 1999), and consistent evidence from randomized controlled trials have demonstrated that calcium supplementation slows postmenopausal bone loss (Dawson-Hughes, et al., 1990; Reid et al., 1993)." See the paragraph [002] and [003] of page 2.

Thus, it is well known that postmenopausal women administer calcium supplementation daily.

Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable, or would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Although Pak et al. does not expressly disclose measuring the high-density lipoprotein level in said woman, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure the high-density lipoprotein level in postmenopausal woman who administering calcium citrate for increasing HDL level.

One having ordinary skill in the art at the time the invention was made would have been motivated to measure the high-density lipoprotein level in a postmenopausal woman who administering calcium citrate for increasing HDL level, since measuring the lipoprotein levels including LDL and HDL in postmenopausal woman is a routine or standard practice in medical art.

Furthermore, measuring cholesterols or lipoproteins levels of patients or humans before, during, and after therapeutic treatments, including with calcium, and determining the administration for at least for two or six months, are well known in the art and are considered well within conventional skills in medical practice and pharmaceutical science, involving merely routine skill in the art.

Response to Argument

Applicant's arguments filed on August 22, 2005 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action May 16, 2005 have been considered but are moot in view of the new ground(s) of rejection above.

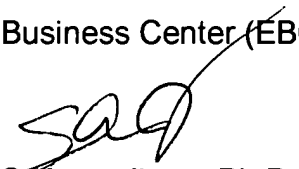
Additionally the declaration of Dr. Ian R. Reid, submitted August 22, 2005 under 37 CFR 1.132, in particular, the data of the change in HDL, LDL, and HDL/LDL presented in the declaration have been fully considered. However, since the inherency issue remained in this case as adequately addressed above, Applicant's claimed unexpected results is not germane to the 102 rejection based on inherency.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
October 26, 2005